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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,838	02/12/2004	Mark K. Wedel	ISIC0008-100(FMDL0001US)	5903

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EXAMINER	
SHIN, DANA H	
ART UNIT	**PAPER NUMBER**
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,838	WEDEL ET AL.	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on March 22, 2007.

Currently, claims 1-3 and 7-8 are pending. Applicants have cancelled claims 4-6.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 112, written description

Claims 1-3 and 7-8 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record as set forth in the Office action mailed on September 22, 2006 and for the reasons stated below.

Applicant's arguments filed on March 22, 2007 have been fully considered but they are not persuasive. Contrary to applicant's assertion that the recitation of "antisense oligonucleotide"

as currently amended would render this rejection moot, the amendments introduced in claim 1 have not satisfied the written description requirement for the following reasons:

The claim language reciting "composition comprises an antisense oligonucleotide of SEQ ID NO:1" embraces any variants or fragments of antisense oligonucleotides having SEQ ID NO:1. Especially, the recitation of "an antisense oligonucleotide of SEQ ID NO:1" reads broadly on different species of antisense oligonucleotides having SEQ ID NO:1.

The instant specification discloses only a single species of antisense oligonucleotide compounds that has been enabled for the presently claimed *in vivo* treatment method, which is identified as ISIS 2302. The specification teaches that ISIS 2302 is a 2'-deoxyoligonucleoitde having a phosphorothioate backbone and the sequence GCCCAAGCTGGCATCCGTCA (SEQ ID NO:1). See paragraph 0054.

The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615; *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004).

Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of treating pouchitis in a human in need thereof comprising any variant/fragment of antisense oligonucleotide having SEQ ID NO:1. For an actual reduction to practice, the invention must have been sufficiently tested to demonstrate that it will work for its intended purpose, but it need not be in a commercially satisfactory stage of development. See, for example, *Scott v. Finney*, 34 F.3d 1058, 1062, 32 USPQ2d 1115, 1118-19 (Fed. Cir. 1994).

Since only a single antisense oligonucleotide compound, ISIS 2302 that consists of SEQ ID NO:1, has been sufficiently tested to demonstrate that it will work for its intended pouchitis treatment in humans, and since ordinary artisans could not predict the operability of any species other than ISIS 2302 in the pouchitis treatment method, claiming a genus of antisense oligonucleotides of SEQ ID NO:1 fails to comply with the written description requirement.

Claim Rejections - 35 USC § 112, enablement

Claims 1-3 and 7-8 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record as set forth in the Office action mailed on September 22, 2006 and for the reasons stated below.

Applicant's arguments filed on March 22, 2007 have been fully considered but they are not persuasive. Contrary to applicant's assertion that the recitation of "antisense oligonucleotide of SEQ ID NO:1" as currently amended would render this rejection moot, the amendments introduced in claim 1 have not satisfied the enablement description requirement for the following reasons:

As stated above for written description rejection, the claim language reciting "composition comprises an antisense oligonucleotide of SEQ ID NO:1" embraces any variants or fragments of antisense oligonucleotides having SEQ ID NO:1. Especially, the recitation of "an antisense oligonucleotide of SEQ ID NO:1" reads broadly on different species of antisense oligonucleotides having SEQ ID NO:1.

While the amended claim reads broadly on a number of different variants and fragments of SEQ ID NO:1, the instant specification discloses only a single antisense oligonucleotide compound that has been enabled for the presently claimed *in vivo* treatment method, which is identified as ISIS 2302 consisting of SEQ ID NO:1 that is modified with phosphorothioates.

Claiming the composition by reciting "composition comprising the antisense oligonucleotide of SEQ ID NO:1" or "composition comprising an antisense oligonucleotide consisting of SEQ ID NO:1" or "composition comprising the antisense oligonucleotide of ISIS 2302" will be remedial.

Double Patenting

Claims 1-3 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3 of U.S. Patent No. 6,169,079 B1 for the reasons of record as set forth in the Office action mailed on September 22, 2006 and for the reasons stated below.

Applicant has requested that this rejection be held in abeyance until such time as allowable subject matter is identified in this case. It was indicated in the previous Office action that a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be

used to overcome this rejection; however, no such terminal disclaimer has been filed by the applicant. Accordingly, this rejection is maintained.

New Rejections Necessitated by Amendments

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 4 of U.S. Patent No. 5,591,623 in view of Patel et al. (*European Journal of Gastroenterology & Hepatology,* 1995, 7:1037-1041),

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed SEQ ID NO:1 is identical to SEQ ID NO:22 claimed in the reference claims of 5,591,623. Although the reference claims do not expressly recite a "method of treating pouchitis in a human in need thereof", the methods claimed in the reference claims embrace the instantly claimed invention because the specification of 5,591,623 discloses that "an animal suspected of having a disease which can be treated by decreasing the expression of ICAM-1" is "treated by administering oligonucleotides in accordance with this invention". See column 7, lines 25-28. Patel et al. teach that patients with pouchitis have significantly high level of plasma ICAM-1. In fact, Patel et al. show that the plasma soluble ICAM-1 level is the highest in patients with pouchitis compared to patients with Crohn's disease, and ulcerative colitis. Since the correlation between the high plasma level of ICAM-1 and pouchitis has been shown by Patel et al. it would have been obvious to practice the claimed invention in U.S. Patent No. 5,591,623 for treating pouchitis as claimed in the instant case. The skilled artisan would have been motivated to do so with a reasonable expectation of success because the specification of 5,591,623 expressly discloses that the method of using SEQ ID NO:22 (ICAM-1 antisense oligonucleotide that is ISIS 2302) can be used to treat ICAM-1 associated disease in an animal.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

J. DOUGLAS SCHULTZ, PH.D.
SUPERVISORY PATENT EXAMINER